

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Shlomo BEN-HAIM, et al.

Serial No.: to be assigned

Examiner: C.H. Layno

Filed: to be assigned

Group Art Unit: 3737

For: ELECTRICAL MUSCLE CONTROLLER

November 28, 2000

Asst. Commissioner for Patents  
Washington, D.C. 20231PRELIMINARY AMENDMENT

SIR:

Prior to determination of the filing fee, please amend the instant application as follows:

IN THE SPECIFICATION:

Page 1, line 1, insert the following:

-- This application is a continuation of commonly assigned, co-pending U.S. Patent Application Serial No. 09/101,723, filed July 8, 1998, incorporated herein by reference, which is a National Phase of PCT Patent Application No. PCT/IL97/00012, filed ~~Jan. 8, 1997~~ <sup>Jan. 8, 1997</sup> February 5, 1997. --

Page 1, line 14, after "1996" insert --, now U.S. Patent No. 5,738,096 --.

Page 10, line 32, change "of" to -- or --.

Page 34, line 25, change "filed" to -- field --.

Page 42, between lines 27 and 28, insert the following paragraph:

-- An implantable light source 57 (Fig. 4B) can be used instead of the electrical controller, which generates pulses of light that are transmitted to at least one light source(s) 59 adjacent to a site of the heart, through waveguides 52a. Similarly, when radio frequency is employed to

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irradiate the heart or a portion thereof, the radio transmitter 59 replaces the electrical controller. --

IN THE CLAIMS:

*Cancel Claims 1 to 58 without prejudice and add the following claims:*

*1* -- 59. A method of modifying the activity of the heart, or of a portion thereof, comprising applying to the Right Ventriculum of said heart a non-excitatory electric field of a magnitude, shape, duty cycle, phase, frequency and duration suitable to obtain a variation in cardiac muscle contraction, wherein said field is applied at a time at which it is unable to generate a propagating action potential.

*2* -- 60. A method according to claim 59, wherein the electric field is applied at the RV Septum.

*3* -- 61. A method according to claim 59 or 60, wherein the step of applying non-excitatory electric field comprises applying an alternated current electric field.

*4* -- 62. A method according to claim 59 or 60, wherein the step of applying non-excitatory electric field comprises applying an electric field that has a temporal envelope selected from the group consisting of exponential temporal envelope, sinusoidal temporal envelope, square temporal envelope, triangular temporal envelope, ramped temporal envelope, sawtooth temporal envelope and biphasic temporal envelope.

*5* -- 63. A method according to claim 59 or 60, wherein *the variation in cardiac muscle contraction* is an increase of the force of contraction of said heart, heart chamber or a portion thereof.

*6* -- 64. A method according to claim 59 or 60, wherein *the desired change is an increase* of the stroke volume of a chamber of the heart.

3. 1 --65. A method according to claim 59 or 60, wherein the desired change is an increase of the output flow of a chamber of the heart.

7- 8 1 2 --66. A method according to claim 59 or 60, wherein the desired change is a change in pressure.

AB 9 8 --67. A method according to claim 66, wherein the pressure is end diastolic pressure or end systolic pressure of a chamber or aortic pressure.

10 1 2 --68. A method according to claim 59 or 60, wherein the desired change is a change of the heart rate.

11 1 2 --69. A method according to claim 59 or 60, comprising sensing the activation of a portion of the heart at a suitable location, and thereafter calculating or estimating therefrom the activation time of the portion of the heart the activity of which it is desired to modify.

12 11 --70. A method according to claim 69, further comprising determining the delay at which the non-excitatory electric field is to be applied from said activation time.

M 1 2 --71. A method according to claim 59 or 60, wherein the activation of the Right Ventriculum is obtained by pacing, and wherein the application of the non-excitatory electric field is synchronized with the pacing signal and is effected with a timing relative to the pacing signal.

15 1 2 --72. A method according to claim 59 or 60, wherein a defibrillating signal is provided to the heart, and wherein the application of the non-excitatory electric field is synchronized with said defibrillating signal.

12 1 2 --73. A method of performing cardiac surgery comprising applying to the Right Ventriculum of the heart a non-excitatory electric field of a magnitude, shape, duty

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cycle, phase, frequency and duration suitable to control the electro-mechanical activity of the tissue in the area on which surgery is to be performed, wherein said field is inhibitory of a propagating action potential, and thereafter performing the required surgical procedure on said area.

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-24. A method of performing cardio-vascular surgery comprising applying to the Right Ventriculum of the heart a non-excitatory electric field of a magnitude, shape, duty cycle, phase, frequency and duration suitable to reduce the output flow, contractility, or pressure thereof, when surgery is performed on tissue perfused by the flow of said chamber, wherein said field is unable to generate a propagating action potential, and thereafter performing the required surgical procedure on said area.

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-25. A method of reducing the output of the Right Ventriculum of a heart, comprising applying to a portion of said Right Ventriculum a non-excitatory electric field of a magnitude, shape, duty cycle, phase, frequency and duration suitable to obtain a desired change, wherein said field is applied at a time at which it is unable to generate a propagating action potential, and wherein reducing the output of the chamber is obtained by reducing the reactivity of said portion, or its sensitivity, to an activation signal, or by reversibly blocking its conduction pathway.

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-26. A method of treating an abnormal activation of the heart, particularly fibrillation, comprising applying to the Right Ventriculum of said heart a non-excitatory electric field of a magnitude, shape and duration suitable to treat the abnormal activation condition, wherein said field is unable to generate a propagating action potential.

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-27. A method according to any of claims 23 to 26, wherein the electric field is applied at the RV Septum.

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-28. A method according to claim 59 or 60, wherein the electric field is applied using electrodes selected from unipolar electrodes or bipolar electrodes.

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13 --79. A method according to claim 69, wherein the activation is sensed by sensing a value of a parameter of an ECG, and wherein the activation time is estimated based on a delay value associated with the value of the parameter.

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--80. A method according to, claim 59 or 60, wherein the application of the non-excitatory field is repeated during a plurality of heart beats, and wherein said repeated application is effected by skipping the application of the field to some of the beats in a train of consecutive heart beats.

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--81. A method of modifying the electro-mechanical activation of the Right Ventriculum of a heart, comprising mapping the activation profile of the Right Ventriculum, determining a desired change in the activation, and modifying the conduction velocity in a non-arrhythmic segment of the Right Ventriculum, wherein the non-excitatory electric field is of a magnitude, shape, duty cycle, phase, frequency and duration suitable to obtain the desired change.

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--82. A method of modifying the activation profile of the Right Ventriculum of a heart, comprising mapping the activation profile of said Right Ventriculum, determining the desired change in the activation profile and changing the refractory period of at least a segment of the Right Ventriculum, wherein the non-excitatory electric field is of a magnitude, shape, duty cycle, phase, frequency and duration suitable to obtain a desired change, and wherein said segment is selected from a segment that is not part of a reentry circuit or an arrhythmia focus in the heart, a segment that is a part of a reentry circuit or an arrhythmia focus in the heart, or an ischemic segment.

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--83. A method of modifying the activation profile of the Right Ventriculum of a heart, comprising mapping the activation profile of said Right Ventriculum, determining the desired change in the activation profile and reversibly blocking the activation of at least a segment of the Right Ventriculum, wherein the non-excitatory electric field is of a magnitude, shape, duty cycle, phase, frequency and duration suitable to obtain a desired change, and wherein said segment is selected from a segment that is not part of a reentry

circuit or an arrhythmia focus in the heart, a segment that is a part of a reentry circuit or an arrhythmia focus in the heart, or an ischemic segment.

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--84. A method of treating a segment of the Right Ventriculum of the heart which induces arrhythmias due to an abnormally low excitation threshold, comprising identifying the segment and applying thereto a desensitizing electric field such that said excitation threshold is increased to a normal range of values.

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1 2 *the variation in cardiac muscle contractile*

--85. A method according to claim 59 or 60, wherein ~~the change~~ comprises selectively and reversibly increasing or reducing the contractility of the Right Ventriculum of the heart relative to another portion or to the left ventricle.

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--86. A method according to claim 59 or 60; further comprising determining a desired range of values for at least one parameter of cardiac activity and controlling at least a local force of contraction of the heart to maintain said parameter within the desired range.

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--87. A method of controlling a heart, comprising applying a non-excitatory electric field to a first portion of the Right Ventriculum of said heart, such that a force of contraction of the first portion is lessened, and applying a non-excitatory electric field to a second portion of the Right Ventriculum, such that a force of contraction of the second portion is increased.

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--88. A method according to claim 59 or 60, wherein the application of the non-excitatory field is repeated during a plurality of heart beats, and wherein said repeated application is effected by reducing the frequency at which the beats are skipped is gradually reduced.

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--89. A method according to claim 59 or 60, wherein the application of the non-excitatory field is repeated during a plurality of heart beats, and wherein said repeated application is effected by changing between beats the size of the portion of the heart to which the field is applied.

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--90. A method according to any of claims 81 to 84, wherein the electric field is applied at the RV Septum. --

## IN THE ABSTRACT

*ne* Add the Abstract set forth on a separate page attached hereto.

Respectfully submitted,

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## ABSTRACT OF THE DISCLOSURE

A method of modifying the force of contraction of at least a portion of a heart chamber, including providing a subject having a heart, comprising at least a portion having an activation, and applying a non-excitatory electric field having a given duration, at a delay after the activation, to the portion, which causes the force of contraction to be increased by at least 5%.

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